Test Type: 14-DAY

P11: STATISTICAL ANALYSIS OF SURVIVAL DATA Test Compound: Pulegone

**CAS Number:** 89-82-7

Date Report Requested: 10/22/2014 Time Report Requested: 12:19:44

First Dose M/F: NA / NA

Lab: BAT

Route: GAVAGE Species/Strain: Rat/F 344/N

C Number: C99020

Lock Date: 10/24/2001

**Cage Range:** ΑII

ΑII **Date Range:** 

**Reasons For Removal:** ΑII

**Removal Date Range:** ΑII

**Treatment Groups:** ΑII

**Study Gender:** Both

**PWG Approval Date NONE** 

Species/Strain: Rat/F 344/N

Test Type: 14-DAY

Route: GAVAGE

P11: STATISTICAL ANALYSIS OF SURVIVAL DATA

Test Compound: Pulegone CAS Number: 89-82-7

Date Report Requested: 10/22/2014
Time Report Requested: 12:19:44

First Dose M/F: NA / NA

Lab: BAT

Male RAT
FIRST TERMINAL SACRIFICE AT 17 DAYS
INDIVIDUAL SURVIVAL TIMES (DAYS)

	INDI	VIDUAL SURVIVAL TIMES (DAYS	5)	
DOSE = 0 MG/KG				
TOTAL 5	UNCENSORED DEATHS 0	CENSORED DEATHS 0	TERMINAL 5	
UNCENSORED DEATH DAYS				
none				
CENSORED DEATH DAYS				
none				
DOSE = 37.5 MG/KG				
TOTAL 5	UNCENSORED DEATHS 0	CENSORED DEATHS 0	TERMINAL 5	
UNCENSORED DEATH DAYS				
none				
CENSORED DEATH DAYS				
none				
DOSE = 75 MG/KG				
TOTAL 5	UNCENSORED DEATHS 0	CENSORED DEATHS 0	TERMINAL 5	
UNCENSORED DEATH DAYS				
none				
CENSORED DEATH DAYS				
none				
DOSE = 150 MG/KG				
TOTAL 5	UNCENSORED DEATHS 0	CENSORED DEATHS 0	TERMINAL 5	
UNCENSORED DEATH DAYS				
none				
CENSORED DEATH DAYS				
none				

<sup>(</sup>A) FIRST TERMINAL SACRIFICE

<sup>(</sup>B) THE FIRST ENTRY IS THE TREND TEST (TARONE, 1975) RESULT. SUBSEQUENT ENTRIES ARE THE RESULTS OF PAIRWISE TESTS (COX, 1972). NEGATIVE TRENDS ARE INDICATED BY "N".

<sup>(</sup>C) MEAN OF ALL UNCENSORED DEATHS PRIOR TO TERMINAL SACRIFICE

<sup>(</sup>D) MEAN OF ALL DEATHS (UNCENSORED, CENSORED, TERMINAL SACRIFICE)

Species/Strain: Rat/F 344/N

Test Type: 14-DAY

Route: GAVAGE

P11: STATISTICAL ANALYSIS OF SURVIVAL DATA

Test Compound: Pulegone CAS Number: 89-82-7

Date Report Requested: 10/22/2014 Time Report Requested: 12:19:44

First Dose M/F: NA / NA

Lab: BAT

Male RAT
FIRST TERMINAL SACRIFICE AT 17 DAYS
INDIVIDUAL SURVIVAL TIMES (DAYS)

		( <b>(</b>	,	
DOSE = 300 MG/KG				
TOTAL 5	UNCENSORED DEATHS 5	CENSORED DEATHS 0	TERMINAL 0	
UNCENSORED DEATH DAYS				
3 3 3	3 4			
CENSORED DEATH DAYS				
none				
DOSE = 600 MG/KG				
TOTAL 5	UNCENSORED DEATHS 5	CENSORED DEATHS 0	TERMINAL 0	
UNCENSORED DEATH DAYS				
2 2 2	3 3			
CENSORED DEATH DAYS				
none				

<sup>(</sup>A) FIRST TERMINAL SACRIFICE

<sup>(</sup>B) THE FIRST ENTRY IS THE TREND TEST (TARONE, 1975) RESULT. SUBSEQUENT ENTRIES ARE THE RESULTS OF PAIRWISE TESTS (COX, 1972). NEGATIVE TRENDS ARE INDICATED BY "N".

<sup>(</sup>C) MEAN OF ALL UNCENSORED DEATHS PRIOR TO TERMINAL SACRIFICE

<sup>(</sup>D) MEAN OF ALL DEATHS (UNCENSORED, CENSORED, TERMINAL SACRIFICE)

Species/Strain: Rat/F 344/N

Test Type: 14-DAY

Route: GAVAGE

P11: STATISTICAL ANALYSIS OF SURVIVAL DATA

Test Compound: Pulegone CAS Number: 89-82-7

Date Report Requested: 10/22/2014 Time Report Requested: 12:19:44

First Dose M/F: NA / NA

Lab: BAT

Male RAT FIRST TERMINAL SACRIFICE AT 17 DAYS

#### KAPLAN-MEIER SURVIVAL PROBABILITY ESTIMATES (%)

DOSE		TIME (DAYS)								
	2	4	6	8	10	12	14	16	18	17(A)
0 MG/KG	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
37.5 MG/KG	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
75 MG/KG	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
150 MG/KG	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
300 MG/KG	100.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
600 MG/KG	40.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0

<sup>(</sup>A) FIRST TERMINAL SACRIFICE

<sup>(</sup>B) THE FIRST ENTRY IS THE TREND TEST (TARONE, 1975) RESULT. SUBSEQUENT ENTRIES ARE THE RESULTS OF PAIRWISE TESTS (COX, 1972). NEGATIVE TRENDS ARE INDICATED BY "N".

<sup>(</sup>C) MEAN OF ALL UNCENSORED DEATHS PRIOR TO TERMINAL SACRIFICE

<sup>(</sup>D) MEAN OF ALL DEATHS (UNCENSORED, CENSORED, TERMINAL SACRIFICE)

Species/Strain: Rat/F 344/N

Test Type: 14-DAY

Route: GAVAGE

P11: STATISTICAL ANALYSIS OF SURVIVAL DATA

Test Compound: Pulegone CAS Number: 89-82-7

Date Report Requested: 10/22/2014 Time Report Requested: 12:19:44

First Dose M/F: NA / NA

Lab: BAT

Male RAT FIRST TERMINAL SACRIFICE AT 17 DAYS

DOSE	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG	
SURVIVAL AT END OF STUDY	100.0%	100.0%	100.0%	100.0%	
(KAPLAN-MEIER)					
SIGNIFICANCE (B)	P=0.000				
(LIFE TABLE)					
MEAN DAY OF NATURAL DEATHS (C)					
(STANDARD ERROR)	(.)	(.)	(.)	(.)	
MEAN LIFE SPAN (D)	17.0	17.0	17.0	17.0	
(STANDARD ERROR)	(0.0)	(0.0)	(0.0)	(0.0)	

<sup>(</sup>A) FIRST TERMINAL SACRIFICE

<sup>(</sup>B) THE FIRST ENTRY IS THE TREND TEST (TARONE, 1975) RESULT. SUBSEQUENT ENTRIES ARE THE RESULTS OF PAIRWISE TESTS (COX, 1972). NEGATIVE TRENDS ARE INDICATED BY "N".

<sup>(</sup>C) MEAN OF ALL UNCENSORED DEATHS PRIOR TO TERMINAL SACRIFICE

<sup>(</sup>D) MEAN OF ALL DEATHS (UNCENSORED, CENSORED, TERMINAL SACRIFICE)

Test Type: 14-DAY

Species/Strain: Rat/F 344/N

Route: GAVAGE

## P11: STATISTICAL ANALYSIS OF SURVIVAL DATA

Test Compound: Pulegone **CAS Number:** 89-82-7

Date Report Requested: 10/22/2014 Time Report Requested: 12:19:44

First Dose M/F: NA / NA

Lab: BAT

#### Male RAT FIRST TERMINAL SACRIFICE AT 17 DAYS

DOSE	300 MG/KG	600 MG/KG	
SURVIVAL AT END OF STUDY	0.0%	0.0%	
(KAPLAN-MEIER)			
SIGNIFICANCE (B)	P=0.009	P=0.011	
(LIFE TABLE)			
MEAN DAY OF NATURAL DEATHS (C)	3.2	2.4	
(STANDARD ERROR)	(0.2)	(0.2)	
MEAN LIFE SPAN (D)	3.2	2.4	
(STANDARD ERROR)	(0.2)	(0.2)	

<sup>(</sup>A) FIRST TERMINAL SACRIFICE

<sup>(</sup>B) THE FIRST ENTRY IS THE TREND TEST (TARONE, 1975) RESULT. SUBSEQUENT ENTRIES ARE THE RESULTS OF PAIRWISE TESTS (COX, 1972). NEGATIVE TRENDS ARE INDICATED BY "N".

<sup>(</sup>C) MEAN OF ALL UNCENSORED DEATHS PRIOR TO TERMINAL SACRIFICE

<sup>(</sup>D) MEAN OF ALL DEATHS (UNCENSORED, CENSORED, TERMINAL SACRIFICE)

P11: STATISTICAL ANALYSIS OF SURVIVAL DATA

Test Compound: Pulegone CAS Number: 89-82-7

Date Report Requested: 10/22/2014 Time Report Requested: 12:19:44

First Dose M/F: NA / NA

Lab: BAT

Species/Strain: Rat/F 344/N

Test Type: 14-DAY

Route: GAVAGE

# Female RAT FIRST TERMINAL SACRIFICE AT 17 DAYS INDIVIDUAL SURVIVAL TIMES (DAYS)

	IND	IVIDUAL SURVIVAL TIMES (DAY)	3)	
DOSE = 0 MG/KG				
TOTAL 5	UNCENSORED DEATHS 0	CENSORED DEATHS 0	TERMINAL 5	
UNCENSORED DEATH DAYS				
none				
CENSORED DEATH DAYS				
none				
DOSE = 37.5 MG/KG				
TOTAL 5	UNCENSORED DEATHS 0	CENSORED DEATHS 0	TERMINAL 5	
UNCENSORED DEATH DAYS				
none				
CENSORED DEATH DAYS				
none				
DOSE = 75 MG/KG				
TOTAL 5	UNCENSORED DEATHS 0	CENSORED DEATHS 0	TERMINAL 5	
UNCENSORED DEATH DAYS				
none				
CENSORED DEATH DAYS				
none				
DOSE = 150 MG/KG				
TOTAL 5	UNCENSORED DEATHS 0	CENSORED DEATHS 0	TERMINAL 5	
UNCENSORED DEATH DAYS				
none				
CENSORED DEATH DAYS				
none				

<sup>(</sup>A) FIRST TERMINAL SACRIFICE

<sup>(</sup>B) THE FIRST ENTRY IS THE TREND TEST (TARONE, 1975) RESULT. SUBSEQUENT ENTRIES ARE THE RESULTS OF PAIRWISE TESTS (COX, 1972). NEGATIVE TRENDS ARE INDICATED BY "N".

<sup>(</sup>C) MEAN OF ALL UNCENSORED DEATHS PRIOR TO TERMINAL SACRIFICE

<sup>(</sup>D) MEAN OF ALL DEATHS (UNCENSORED, CENSORED, TERMINAL SACRIFICE)

none

P11: STATISTICAL ANALYSIS OF SURVIVAL DATA

Test Compound: Pulegone CAS Number: 89-82-7

Time Report Requested: 12:19:44

Date Report Requested: 10/22/2014

First Dose M/F: NA / NA

Lab: BAT

Species/Strain: Rat/F 344/N

Test Type: 14-DAY

Route: GAVAGE

Female RAT FIRST TERMINAL SACRIFICE AT 17 DAYS INDIVIDUAL SURVIVAL TIMES (DAYS)

DOSE = 300 MG/KG				
TOTAL 5	<b>UNCENSORED DEATHS 4</b>	CENSORED DEATHS 0	TERMINAL 1	
UNCENSORED DEATH DAYS				
3 3 3	4			
CENSORED DEATH DAYS				
none				
DOSE = 600 MG/KG				
TOTAL 5	UNCENSORED DEATHS 5	CENSORED DEATHS 0	TERMINAL 0	
UNCENSORED DEATH DAYS				
2 2 2	3 3			
CENSORED DEATH DAYS				

<sup>(</sup>A) FIRST TERMINAL SACRIFICE

<sup>(</sup>B) THE FIRST ENTRY IS THE TREND TEST (TARONE, 1975) RESULT. SUBSEQUENT ENTRIES ARE THE RESULTS OF PAIRWISE TESTS (COX, 1972). NEGATIVE TRENDS ARE INDICATED BY "N".

<sup>(</sup>C) MEAN OF ALL UNCENSORED DEATHS PRIOR TO TERMINAL SACRIFICE

<sup>(</sup>D) MEAN OF ALL DEATHS (UNCENSORED, CENSORED, TERMINAL SACRIFICE)

Species/Strain: Rat/F 344/N

Test Type: 14-DAY

Route: GAVAGE

P11: STATISTICAL ANALYSIS OF SURVIVAL DATA

Test Compound: Pulegone CAS Number: 89-82-7

Date Report Requested: 10/22/2014 Time Report Requested: 12:19:44

First Dose M/F: NA / NA

Lab: BAT

Female RAT FIRST TERMINAL SACRIFICE AT 17 DAYS

#### KAPLAN-MEIER SURVIVAL PROBABILITY ESTIMATES (%)

DOSE		TIME (DAYS)								
	2	4	6	8	10	12	14	16	18	17(A)
0 MG/KG	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
37.5 MG/KG	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
75 MG/KG	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
150 MG/KG	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
300 MG/KG	100.0	20.0	20.0	20.0	20.0	20.0	20.0	20.0	20.0	20.0
600 MG/KG	40.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0

<sup>(</sup>A) FIRST TERMINAL SACRIFICE

<sup>(</sup>B) THE FIRST ENTRY IS THE TREND TEST (TARONE, 1975) RESULT. SUBSEQUENT ENTRIES ARE THE RESULTS OF PAIRWISE TESTS (COX, 1972). NEGATIVE TRENDS ARE INDICATED BY "N".

<sup>(</sup>C) MEAN OF ALL UNCENSORED DEATHS PRIOR TO TERMINAL SACRIFICE

<sup>(</sup>D) MEAN OF ALL DEATHS (UNCENSORED, CENSORED, TERMINAL SACRIFICE)

P11: STATISTICAL ANALYSIS OF SURVIVAL DATA

Test Compound: Pulegone CAS Number: 89-82-7

Date Report Requested: 10/22/2014 Time Report Requested: 12:19:44

First Dose M/F: NA / NA

Lab: BAT

Species/Strain: Rat/F 344/N

Test Type: 14-DAY

Route: GAVAGE

# Female RAT FIRST TERMINAL SACRIFICE AT 17 DAYS

DOSE	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG	
SURVIVAL AT END OF STUDY	100.0%	100.0%	100.0%	100.0%	
(KAPLAN-MEIER)					
SIGNIFICANCE (B)	P=0.000				
(LIFE TABLE)					
MEAN DAY OF NATURAL DEATHS (C)					
STANDARD ERROR)	(.)	(.)	(.)	(.)	
MEAN LIFE SPAN (D)	17.0	17.0	17.0	17.0	
STANDARD ERROR)	(0.0)	(0.0)	(0.0)	(0.0)	

<sup>(</sup>A) FIRST TERMINAL SACRIFICE

<sup>(</sup>B) THE FIRST ENTRY IS THE TREND TEST (TARONE, 1975) RESULT. SUBSEQUENT ENTRIES ARE THE RESULTS OF PAIRWISE TESTS (COX, 1972). NEGATIVE TRENDS ARE INDICATED BY "N".

<sup>(</sup>C) MEAN OF ALL UNCENSORED DEATHS PRIOR TO TERMINAL SACRIFICE

<sup>(</sup>D) MEAN OF ALL DEATHS (UNCENSORED, CENSORED, TERMINAL SACRIFICE)

Species/Strain: Rat/F 344/N

Test Type: 14-DAY

Route: GAVAGE

P11: STATISTICAL ANALYSIS OF SURVIVAL DATA

Test Compound: Pulegone CAS Number: 89-82-7

Date Report Requested: 10/22/2014 Time Report Requested: 12:19:44

First Dose M/F: NA / NA

Lab: BAT

Female RAT FIRST TERMINAL SACRIFICE AT 17 DAYS

DOSE	300 MG/KG	600 MG/KG	
SURVIVAL AT END OF STUDY	20.0%	0.0%	
(KAPLAN-MEIER)			
SIGNIFICANCE (B)	P=0.053	P=0.011	
(LIFE TABLE)			
MEAN DAY OF NATURAL DEATHS (C)	3.3	2.4	
(STANDARD ERROR)	(0.3)	(0.2)	
MEAN LIFE SPAN (D)	6.0	2.4	
(STANDARD ERROR)	(2.8)	(0.2)	

<sup>(</sup>A) FIRST TERMINAL SACRIFICE

<sup>(</sup>B) THE FIRST ENTRY IS THE TREND TEST (TARONE, 1975) RESULT. SUBSEQUENT ENTRIES ARE THE RESULTS OF PAIRWISE TESTS (COX, 1972). NEGATIVE TRENDS ARE INDICATED BY "N".

<sup>(</sup>C) MEAN OF ALL UNCENSORED DEATHS PRIOR TO TERMINAL SACRIFICE

<sup>(</sup>D) MEAN OF ALL DEATHS (UNCENSORED, CENSORED, TERMINAL SACRIFICE)

**Test Type:** 14-DAY **Route:** GAVAGE

Species/Strain: Rat/F 344/N

### P11: STATISTICAL ANALYSIS OF SURVIVAL DATA

Test Compound: Pulegone CAS Number: 89-82-7

Date Report Requested: 10/22/2014 Time Report Requested: 12:19:44

First Dose M/F: NA / NA

Lab: BAT

\*\* END OF REPORT \*\*

<sup>(</sup>A) FIRST TERMINAL SACRIFICE

<sup>(</sup>B) THE FIRST ENTRY IS THE TREND TEST (TARONE, 1975) RESULT. SUBSEQUENT ENTRIES ARE THE RESULTS OF PAIRWISE TESTS (COX, 1972). NEGATIVE TRENDS ARE INDICATED BY "N".

<sup>(</sup>C) MEAN OF ALL UNCENSORED DEATHS PRIOR TO TERMINAL SACRIFICE

<sup>(</sup>D) MEAN OF ALL DEATHS (UNCENSORED, CENSORED, TERMINAL SACRIFICE)